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ENVIRONMENTAL PROTECTION AGENCY
JAN 1 1994
MONTANA OFFICE

Ref: 8HWM-SM

MEMORANDUM

SUBJECT: Revised Soil Lead Guidance for CERCLA sites & RCRA facilities

FROM: Paul S. Arell, Chief
Technical Section

Paul S. Arell

TO: Addressees

Attached is the most recent version of the OSWER directive entitled "Revised Soil Lead Guidance for CERCLA sites and RCRA facilities". Please review this draft and provide comments to Susan Griffin no later than January 19th. She will be collecting comments for division and providing response back to Headquarters.

cc: Chris Weis
Gerry Henningsen
Matt Cohn (ORC)
Joe Santarella (ORC)
Russ Forba (8MO)
Marc Alston (S2D)
John Giedt (ERB)

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OSWER SOIL LEAD DIRECTIVE BRIEFING

BACKGROUND

1. The Directive in effect (issued September 1989) recommends a soil lead cleanup level of 500-1000 ppm.
2. ARCO sued EPA over the "limitations" imposed by the 500-1000 ppm and the process used to develop the guidance. EPA agreed to withdraw the September 1989 Directive by April 1992 and issue a new Directive by December, 1992.
3 EPA issued new draft in June, 1992 recommending 500 ppm as a PRG.
4. Draft was criticized for setting one national PRG.
5. This proposed interim guidance sets screening levels (similar to the other 30 soil screening levels) for residential and non-residential sites and presents an approach for developing site-specific PRGs, addressing multiple lead sources.
6. The Directive uses the Integrated Exposure Uptake Biokinetic (IEUBK) model, that has been reviewed by the Science Advisory Board, to determine PRGs.

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ISSUES/RECOMMENDATIONS

1. Timing/Title X

   Issue: Release Interim Directive now OR wait for the Office of Pollution Prevention and Toxic Substances to complete the rules under Title X requiring health-based levels for lead in soil, paint and dust. The Directive is one of the Superfund Administrative Improvements Initiatives, scheduled for completion by December 31, 1993.

   Recommendation: Release Directive now as interim. When Title X regulations are promulgated, revise as necessary and issue as final.

2. Non-residential Number

   Issue: Include non-residential screening number and approach for developing site-specific PRGs in the Interim Directive OR release as separate Directive OR wait until adult model is developed over the next few years.

   Recommendation: 1. Issue directive with non-residential screening number (preferred by RCRA and the Regions) OR 2. To prevent possible delay, take a more "conservative" approach and issue the directive with a non-residential number separately to allow more time for comment.

3. Paint

   Issue: Can the Fund be used to remediate indoor paint under special circumstances IF paint is a significant risk contributor, IF it is cost-effective AND IF no other sources of funding are available? Will SARA allow the Fund to be used for that purpose?

   Recommendation: In the interests of public health, we should raise this issue during reauthorization due to the environmental justice concerns.

OSWER Directive XXXXXXXXX

MEMORANDUM

SUBJECT: Revised Soil Lead Guidance for CERCLA Sites and RCRA Facilities

FROM: Elliott Laws, Assistant Administrator
Office of Solid Waste and Emergency Response

TO: Regional Administrators (1-X)

PURPOSE

As part of the Superfund Administrative Improvements Initiative, this interim directive establishes a streamlined approach for determining protective levels for lead in soil at Superfund sites and RCRA Corrective Action facilities. It sets screening levels for lead in soil for both residential and non-residential land uses, and describes how to develop site-specific preliminary remediation goals (PRGs). The establishment of the screening level in this guidance is consistent with the recent Draft Soil Screening Levels Guidance (Quick Reference Fact Sheet, OSWER, September, 1993). Further, this interim directive replaces all previous directives on soil lead cleanup for these programs.

Because of the recent availability of EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model for lead, OSWER has decided to use the model with site data to establish site-specific PRGs and with national default parameters to establish a residential screening level. To set a non-residential screening level, however, the interim directive uses a simple linear equation. These screening levels, however, are not automatically cleanup goals or cleanup standards, which generally include evaluation of the nine remedy selection criteria. Rather, these screening levels have been developed to determine which sites or portions of sites do not require further study, and to encourage voluntary cleanup. This interim directive also recognizes that alternative methods for evaluating risks at lead sites may also be appropriate.

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The interim directive addresses the potential role of multiple sources of lead (e.g., interior and exterior paint and indoor dust) in contributing to elevated blood lead levels at a site. It offers a flexible approach (known alternately as the "bubble" concept) that allows in some cases for remediation of lead sources, other than or in addition to soil, that contribute significantly to elevated blood lead. For a detailed discussion of the decision logic developed for addressing lead-contaminated sites, see the Implementation section and Appendix A.

In addition, this interim directive clarifies the relationship between Superfund cleanups and EPA's efforts under the Residential Lead-based Paint Hazard Reduction Act of 1992 (Title X) which mandates the development of health-based standards for bare residential soil, paint and dust by April, 1994. Once these standards are developed, OSWER intends to issue a final directive. Until the standards are published, OSWER believes risk decisionmakers at lead-contaminated sites need updated guidance that takes advantage of the developments in the IEUBK model, the preliminary findings from the Urban Soil Lead Abatement Demonstration Project and the cumulative experience of the Superfund and RCRA Corrective Action programs dealing with the significant differences at lead-contaminated sites.

BACKGROUND

1989-1991. A soil lead cleanup level of 500 - 1000 ppm for residential CERCLA sites was recommended for protection of human health in the September 1989 OSWER Directive #9355.4-02. The August 29, 1991, supplemental guidance discussed EPA's efforts to develop a new directive that would (1) account for the contribution of multiple media to total lead exposure, and (2) provide a stronger scientific basis for determining a soil lead cleanup level at a specific site. Use of the EPA IEUBK model, which integrates exposure from lead in air, water, soil, dust, diet and paint with pharmacokinetic modeling to predict blood lead levels in the most sensitive population (i.e., children 6 - 84 months old), was identified as the best available approach for accomplishing these objectives at that time.

In the spring of 1991, to assist regional risk assessors and site managers in their use of the model and with data collection decisions at Superfund and RCRA sites, OSWER organized a Technical Review Workgroup composed of scientists and risk assessors from the Regions, ORD, and Headquarters.

In November 1991, the EPA Science Advisory Board (SAB) reviewed the scientific merits of using the IEUBK model for

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assessing total lead exposure and developing soil lead cleanup levels at CERCLA and RCRA sites. In general, the SAB found use of the model to be an important advance in assessing potential health risks from environmental contaminants. However, the SAB also expressed concern over possible misuse of the model.

In response to SAB concern over the potential for incorrect use of the model and selection of inappropriate input values both for default and site-specific applications, OSWER is developing a comprehensive "Guidance Manual for Site-specific Use of the EPA IEUBK Model" (referred to in this interim directive as the "Guidance Manual"). This Guidance Manual will provide strategies, protocols, and analytical methods for sampling lead from soil, house dust, paint, homegrown produce, air, water, and blood. In addition, it will discuss the use of model default values or alternative values, and the application of the model to characterize site risks and evaluate the protectiveness of site-specific soil cleanup levels. Use of the Guidance Manual with assistance, if necessary, from the Technical Review Workgroup, should facilitate consistent use of the IEUBK model and allow the risk assessor to obtain valid and reliable predictions of lead exposure. This workgroup has been collecting Regional data to further validate the model, and update the Guidance Manual as needed.

<u>1992-Present</u>. Following discussions among senior Regional and OSWER management, OSWER recommended in the spring of 1992 that a "two step" decision framework be developed for establishing cleanup levels at sites with lead-contaminated soils. This framework would identify a single level of lead in soils to be used as either the preliminary remediation goal for Superfund cleanups or the action level for RCRA corrective action sites, but would also recommend/allow site managers to establish site-specific cleanup levels (where appropriate) based on site-specific circumstances. Use of the IEUBK model would be an integral part of this framework. The Agency then developed a draft which it circulated for review on June 4, 1992 that set 500 ppm as a preliminary remediation goal and an action level for RCRA facilities at residential sites.

Following development of this draft, the Agency held a "broadening" meeting on July 31, 1992 with a wide range of interests including environmental groups, representatives from the lead industry and citizens. The outcome of this meeting encouraged the Agency to think more broadly about how the directive would affect urban areas, how lead paint and dust contribute to overall risk, and how blood lead data could be used in risk assessment. In subsequent meetings with ATSDR and CDC,

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consensus was reached on how to use blood lead data and the need to evaluate the contribution of paint. In addition, during the course of these meetings a decision tree approach was suggested that proposed different threshold levels (primary and secondary) based on the need for screening, action and land use patterns.

Findings from the three cities of the Urban Soil Lead Abatement Demonstration Project (which is currently being peer reviewed) indicate that dust and paint are major contributors to elevated blood lead levels in children and that any strategy to reduce overall lead risk at a site needed to consider not only soil, but these other pathways in order to be protective. (For further information on the 3 City Lead Study, contact Dr. Rob Elias, ECAO, RTP, (919) 541-4167.)

Finally, in its efforts to develop the interim directive, the OSWER Soil Lead Workgroup not only met with other agencies, but also with other EPA workgroups including Title X, Large Area Lead Sites, and Urban Lead. Consequently, this interim directive represents an integrated approach that addresses the needs of many constituencies.

<u>)erivation of Screening Levels</u>

<u>Residential:</u> The residential screening level used in this interim directive is based on the IEUBK model. The model is designed for children (age 6 months to 7 years) in a residential setting by using national average values for lead concentration in water (4 ug/l) and air (.2 ug/cubic meter) and average age-specific dietary intake rates (range of 5.88 - 7.42 ug/day). The model uses a conservative estimate for bioavailability of lead in soil (30%) and for the correlation between house dust and soil lead concentrations (70%). Default assumptions exclude any exposure to paint. The model uses a geometric standard deviation of 1.6. and identifies a greater than 5% probability that a child's blood lead levels may exceed 10 ug/dl (or that greater than 5% of potentially exposed children may experience blood lead levels greater than 10 ug/dl). The Guidance Manual provides a more detailed discussion of the model and its input parameters.

<u>on-residential:</u> The non-residential screening level is based on adult exposure to lead and is calculated using a simple linear equation, similar to the equation used to predict blood lead in children during the early stages of development of the IEUBK model. (The equation and input assumptions are presented in Appendix B of this interim directive.) Because this is a crude, though logical, way of calculating blood lead levels in adults, the input assumptions for this equation rely upon conservative

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estimates of health effects found in adults, as documented in Appendix B. To produce a more accurate estimate of adult blood lead levels from multiple sources, EPA has initiated work on a comprehensive adult model. This adult model will not be ready for some time. However, when this work is completed, the agency plans to revise the non-residential screening level to reflect the best available science.

OBJECTIVE

With this interim directive, OSWER recommends that 400 ppm soil lead (based on application of the IEUBK model) be used as a screening level for lead in soil for residential scenarios at CERCLA and an action level at RCRA corrective action sites. For non-residential sites, the interim directive recommends a soil lead level of 2000 ppm as a screening level for CERCLA and RCRA corrective action sites. Residential sites with soil lead below 400 ppm and non-residential sites below 2000 ppm generally require no further action. However, there may be special situations where further study may be warranted below these screening levels. For example, agricultural areas, wetlands with ecological risk, sandboxes and playgrounds are all situations that would require further study. For further guidance on ecological risks, risk decisionmakers are encouraged to consult Regional Biological Team Assistance Groups (BTAGs).

Frequently, the groundwater pathway will not pose a significant risk since many lead compounds are generally not highly mobile. However there are situations where, because of the form of lead and/or hydrogeology at the site, lead may pose a threat to the groundwater. In these situations, additional analysis is warranted.

While recognizing that urban lead is a significant problem, non-Superfund urban areas (those without industrial sources) sites with elevated lead levels fall outside the realm of this interim directive. Promulgation of regulations under Title X Section 403 will be an appropriate tool for defining these sites. Furthermore, efforts to develop the interim directive and Title X have been coordinated and are consistent.

Superfund

OSWER recommends using the IEUBK model during the RI for evaluating potential risks to humans from environmental exposures to lead. Site-specific data must be collected to determine site-specific PRGs. At a minimum, this will generally involve collection of soil and dust samples in appropriate areas of the

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site. Further guidance on data collection can be obtained by contacting the Regional Toxics Integration Coordinator who in turn may consult the OSWER Lead Technical Review Workgroup. Where the IEUBK model identifies a greater than 5% probability that a child's blood lead levels may exceed 10 ug/dl (or that greater than 5% of potentially exposed children may experience blood lead levels greater than 10 ug/dl), remedial action is generally recommended.

RCRA Corrective Action.

OSWER also recommends that 400 ppm lead in soil be used as an action level for RCRA Corrective Action. In the Corrective Action program, the action level is a screening level and trigger for further study. Generally, therefore, soil levels below 400 ppm would indicate no further action while soil levels above 400 ppm would indicate that, based on further study, action may be necessary. In addition, the action level serves as a point of departure for establishing a remediation goal. The final decision about what remediation goal is appropriate at a particular site depends on a number of factors including remedy selection criteria such as reliability, effectiveness, implementability and cost.

IMPLEMENTATION

Superfund

OSWER recommends from this time forward, a soil lead concentration of 400 ppm be used as a screening level for residential Superfund sites and a soil lead concentration of 2000 ppm be used as a screening level for non-residential sites. Further, OSWER recommends that the EPA IEUBK model be used to assess total lead exposure and to assist the site manager in developing soil lead cleanup levels at residential sites. The decision logic for addressing residential and non-residential lead sites is contained in the appendix.

In reviewing the status of all CERCLA RI/FS work, application of the interim directive is not recommended if risk assessments have been completed. For removal sites, this interim directive recommends that the removal program defer decisions regarding removal actions to the Regional Decision Team (RDT). The RDT will then refer sites to the removal program for early action, once the RDT has determined an appropriate PRG by using site-specific data to run the IEUBK model.

The approach taken in this interim directive helps meet the

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goals set by the Superfund Accelerated Cleanup Model (SACM) for streamlining remedial decisionmaking. However, in situations where a PRP believes a soil cleanup level above the PRG derived from running the IEUBK model is appropriate for a given site, the PRP would generally assume the burden of collecting additional site-specific data and evaluating it, and presenting the case to the Agency. Alternatively, EPA may require soil cleanup levels to be set below the PRG or below the screening level if site-specific circumstances warrant. For further information on the use of the IEUBK model at Superfund sites, call Susan Griffin, chair of the Lead Technical Review Workgroup, USEPA Region VIII, (303) 294-1062.

RCRA Corrective Action

OSWER recommends that 400 ppm be used as the action level for RCRA Corrective Action. The final decision about cleanup levels at particular sites will be made after factoring in any appropriate site-specific data (e.g., data on bioavailability) and information on the reliability, effectiveness and cost of remedial alternatives. Generally, we expect 400 ppm to serve as the "floor" for soil lead cleanups at RCRA Corrective Action facilities with higher levels being set when appropriate based on site-specific considerations. In some cases, site circumstances will suggest the need to use the IEUBK model on a site-specific basis.

To help meet the goals set by the Agency for accelerated cleanups by streamlining remedial decision making to save time and resources, site-specific use of the IEUBK model at RCRA facilities would be recommended only on an exception basis. In situations, however, where an owner/operator or EPA believes a level either above or below 400 ppm is appropriate for residential land use, the owner/operator would generally assume the burden of collecting data and evaluating it, using the IEUBK model. Site-specific circumstances might include, for example, situations where there is ecological risk, risks from multiple contaminants, or additional significant routes of exposure not accounted for by the IEUBK model such as the movement of soil lead to groundwater.

Issues for Both Programs

Cleanup of soils vs. other lead sources: Generally speaking, there are two types of site-specific exposure data that may be collected to evaluate site risks and the protectiveness of soil cleanup levels. These are data relating to health risk from soils, and data related to health risk from other sources such as

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water distribution systems, household dust and lead-based paint. In situations where significant risks are posed by lead sources other than soil lead, it may be appropriate to remediate one or more of these sources at CERCLA (fund- or PRP-lead) sites or RCRA facilities. Measures can be divided into those which remove the source of contamination (abatement) and those which leave the contamination in place but block the exposure pathway (intervention). These combinations of measures might include but not be limited to:

Abatement - Soil removal, indoor cleaning (dust removal), or interior and exterior lead paint abatement.

Intervention - Institutional controls, education/public outreach, blood lead monitoring, gardening restrictions, grass or other cover, or additional soil cover.

Combinations of measures should be developed and assessed against their ability to meet the Remedial Action Objective and the nine remedy selection criteria. Key criteria for lead sites are typically protectiveness, ARARS (for CERCLA), permanence, implementability, cost effectiveness, and state and community acceptance. The existence of a threat from lead in soil does not necessarily mean that the most appropriate response is excavation. Addressing exposure from other sources may be cheaper and reduce risk to a greater extent. Soils should not be cleaned up to low levels that provide little or no risk reduction in order to compensate for limited action on other significant lead sources, e.g., drinking water or lead-based paint in residential housing.

Lead-based paint can be a significant source of lead exposure and needs to be considered when determining the most appropriate response action. Interior paint can contribute to elevated indoor dust lead levels. Exterior paint can be a significant source of recontamination of soil. Appendix A of this document contains more information on how to evaluate the contribution of paint.

An option shown to be effective in reducing blood lead levels in some communities (regardless of source) is the development and promotion of public education and awareness programs that focus on the causes and prevention of lead poisoning in children. Information on abatement of lead-based paint by the homeowner as well as inexpensive preventive measures the public can take to reduce their exposure to lead is available from EPA's Office of Pollution Prevention and Toxics (OPPT). Further, OPPT is assessing the effectiveness of various lead

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paint abatement options emphasizing low cost methods. For additional information, contact the National Lead Information Center at 1-800-424-LEAD.

Mining-related sites: Both risk assessors and site managers should be aware that the correlation between soil lead concentrations and blood lead levels at certain mining-related sites currently seems to be weaker than those correlations seen at active smelter or other lead exposure sites. Possible reasons for this could be the variability in soil lead contribution to house dust levels, or differences in the bioavailability of lead from soil that may result from differences in the size or mineral composition of soil particles. See discussion in next section, Use of Blood Lead Data for assessing differences between measured and predicted blood lead levels.

Thus for mining-related sites without significant past smelting/milling activity, this interim directive recommends that the soils also be characterized for particle size and speciation, in addition to determining lead concentrations for both soil and house dust. The Guidance Manual will provide information on the collection and use of relevant data.

Site managers and risk assessors are cautioned that most areas impacted by mining activities are also associated with recent or historical smelting or milling operations. Generalizations regarding distinct differences between mining and smelting or milling sites should be avoided until adequate site history and characterization is complete.

Use of blood lead data: In conducting remedial investigations, the interim directive recommends evaluating available blood lead data. In some cases, it may be appropriate to collect new or additional blood lead samples. In general, data from well-conducted blood lead studies of children on or near a site can provide useful information to both the risk assessor and site decision maker. However, the design and conduct of such studies, as well as the interpretation of results, are often difficult because of confounding factors such as a small population sample size. Therefore, any available blood lead data should be carefully evaluated by experts and approved by the Region. Chapter 9 of the Guidance Manual discusses how observed blood lead survey data should be evaluated against the predictions of the IEUBK model. Where blood lead data are available, the data should be provided to the Technical Review Workgroup for consideration in future IEUBK model validation exercises.

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As Chapter 9 of the Guidance Manual cautions, it is not
commended that blood lead data be used alone either to assess
sk from lead exposure or to develop soil lead cleanup levels.
e Science Advisory Board in its review of the IEUBK model
ncluded that temporary modification of site resident behavior
erhaps as a result of site listing on the National Priorities
st) could mask the true magnitude of potential risk at a site
d lead to only temporary reductions in the blood lead levels of
ildren. In addition, normal blood lead levels (below 10 ug/dl)
not necessarily indicate an absence of risk from the site.

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APPENDIX

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Appendix A-1
Decision Logic for All Lead Sites

Step 1: Determine soil lead concentration at the site.

Step 2: Collect site-specific data.

Step 3: Use default number as PRG or run the IEUBK model to determine the PRG.

Step 4: Evaluate any available blood lead data.

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Appendix A-2
Decision Logic for Residential Lead Sites

Step 1: Determine soil lead concentration at the site.

If soil lead is less than 400 ppm: STOP. No further action is required.

If soil lead is greater than 400 ppm: PROCEED to Step 2, unless 400 ppm is selected as a cleanup goal.

Step 2: Collect site-specific data.

Sampling Data

- Environmental and dust sampling
- Unique site situations (e.g., speciation and particle sizing)

Available blood lead data

If both the IEUBK model and available blood lead data indicate greater than 5% of the population with blood lead levels greater than 10 ug/dl, take action to reduce lead exposure; if less than 5% of the population with blood lead levels greater than 10 ug/dl, no further action is required.

If the model predicts elevated blood lead levels, but available blood lead data is not elevated or blood lead data is not available, conduct further site-specific study.

If measured blood leads are elevated, but the model does not predict elevated levels, consult the Guidance Manual on what constitutes a "good" blood lead study and conduct further site-specific study to determine the source of the lead (e.g., paint, leaded pipes in homes).

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Step 3: Run the IEUBK model to determine the PRG.

If lead-based exterior paint is the only major contributor to exposure, no Superfund action is warranted.

If soil is the only major contributor to elevated blood lead, soil remediation is warranted, but paint abatement is not.

If both lead-based paint and soil are major contributors to exposure, consider remediating both sources.

If indoor dust levels are greater than soil levels, consider evaluating the contribution of interior lead-based paint to the dust levels. If interior lead-based paint is a major contributor, consider remediating indoor paint to achieve a greater overall risk reduction at lower cost. (SEE DECISION LOGIC FOR LEAD-BASED PAINT.)

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Appendix A-3
Decision Logic for Non-residential Lead Sites

Step 1: Determine soil lead concentration at the site.

If soil lead is less than 2000 ppm STOP. No further action is required.

If soil lead is greater than 2000 ppm PROCEED to Step 2, unless ppm is selected as a cleanup goal.

Step 2: Collect site-specific data.

- Environmental and dust sampling
- Unique site situations (e.g., speciation and particle sizing)

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Appendix A-4
Decision Logic for Lead-based Paint

If soil lead levels are below screening levels, paint must be addressed under authorities other than CERCLA.

If soil lead levels are above screening levels:

1. Examine condition of exterior paint.

   - If paint is deteriorated, assess contribution or potential contribution of paint to elevated soil lead levels through speciation studies.

2. Evaluate potential for recontamination of soil by exterior paint.

3. Remediate exterior paint only in conjunction with soil.

   - Determine appropriate remediation based on applying the 9 criteria, remediating the major contributor first.

4. Examine condition of indoor paint:

   - If indoor dust lead concentration is greater than outdoor soil lead concentration, remediate indoor dust (e.g., through a removal action, or making Hepa-vacs available to community).

5. Once the risk from indoor paint has been assessed, examine authorities to abate indoor paint (e.g., PRP, State, local, HUD, Title X).

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Appendix B
Calculation of Non-residential Screening Level

The following equations describe how the soil and dust lead concentration is determined by assuming a given blood lead "level of concern" for an adult. Equation (1) explains that the blood lead level of concern for adults is the sum of the contributions from soil and dust and from all other sources. Rearranging the equation, and solving for the blood lead level for soil and dust yields equation (2).

<u>Equation 1</u>

$$\text{Bd-Pb level of Concern for Adults} = \text{Bd-Pb level for Adults due to Soil and Dust} + \text{Bd-Pb level for Adults from All Other Sources}$$

<u>Equation 2</u>

$$\text{Bd-Pb level for Adults due to Soil and Dust} = \text{Bd-Pb level of Concern for Adults} - \text{Bd-Pb level for Adults from All Other Sources}$$

The blood lead level for adults can also be described by the following equation, equation (3) which relates soil and dust concentration, ingestion, absorption by the adult body and the release of lead from the body (an "inverse clearance factor").

<u>Equation 3</u>

$$\text{Bd-Pb level for Adults due to Soil and Dust} = \text{Soil Pb Concentration} \times \text{Absorption by Adults} \times \text{Adult Ingestion Rate} \times \text{Inverse Clearance Factor}$$

Setting equation (2) equal to equation (3) and solving for the soil lead concentration yields equation (4):

<u>Equation 4</u>

$$\text{Soil Pb Concentration} = \frac{\text{Bd-Pb Level of Concern for Adults} - \text{Bd-Pb Level for Adults from All Other Sources}}{\text{Absorption by Adults} \times \text{Adult Ingestion Rate} \times \text{Inverse Clearance Factor}}$$

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The assumptions for this equation are as follows: (1) The blood lead level of concern is 15 ug/dl based on hypertension studies of adult white males (Ref. 1). (2) The blood lead level for adults from other sources is 2.8 ug/dl based on the following references (Ref. 2). (3) The absorption for adults is assumed to be 10% based on studies by Rabinowitz (Ref. 3). (4) Adult ingestion rate of 50 mg/day is from Ref. 4, which is derived from References 5,6 and 7. (5) The inverse clearance factor of 40 days/90 liters is documented in references 8, 9, 10 and 11.

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